510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

OCT 5 2012

I. General Information

Submitter: BTL Industries, Inc.
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Summary Preparation Date: December 22, 2011

II. Device Information

Trade Name:	BTL Elite
Common/Usual Name:	Shortwave Diathermy
Classification:	Class II
	21 CFR 890.5290
Product Code:	IMJ
Classification Name:	Shortwave Diathermy
Device Panel:	Physical Medicine

III. Predicate Devices

Device name	**BTL Elite**	**Intelect SWD 100**	**AutoTherm 395**
Company name	**BTL Industries Ltd**	**Chattanooga Group**	**Mettler Electronics Corp.**
510(k) reference	K120093	K083433	K022458
Device description	Device consists of a power supply that provides power to an electromagnetic energy generator. (27.12 MHz)	Device consists of a power supply that provides power to an electromagnetic energy generator. (27.12 MHz)	Device consists of a power supply that provides power to an electromagnetic energy generator. (27.12 MHz)
Class	II	II	II
Product Code	IMJ	IMJ	IMJ
Indications for use	Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.	Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases.	Indications for use – Shortwave diathermy delivers energy in the radio band of 27.12 MHz to provide deep heating therapeutic effects to body tissues. When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.
Mechanism of Action	Deep heating of tissue by therapeutic application of radio frequency electrical currents	Deep heating of tissue by therapeutic application of radio frequency electrical currents	Deep heating of tissue by therapeutic application of radio frequency electrical currents
Power	400 W (pulsed) 200 W (continuous)	200 W (pulsed) 100 W (continuous)	400 W (pulsed) 200 W (continuous)
Dimensions W x H x D	560 x 980 x 560 mm	420 x 1143 x 410 mm	380 x 850 x 390 mm
Configuration	Cabinet-mounted with wheels	Cabinet-mounted with wheels	Cabinet-mounted with wheels
Device classification	Class II, IMJ, 890.5290	Class II, IMJ, 890.5290	Class II, IMJ, 890.5290

IV. Intended Use

The BTL Elite is intended for use in applying therapeutic deep heat for selected medical conditions by applying electromagnetic energy in the radio frequency band of 27.12 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

V. Device Description

The BTL Elite is a shortwave diathermy system intended for the therapeutic application of deep heating. The control unit consists of the control system and the electronic system. The control system contains the main microprocessor and software for control of the entire equipment; the electronic system contains the complete electronics for electromagnetic field generation. The device is operated via a 5.7 inch color touch screen and graphic user interface that allows for maximum operator comfort. A large control knob is provided to increase and decrease output power.

A neon check light is provided to verify that radiofrequency energy is being transmitted between the capacitive applicators. If such energy is transmitted, the indicator illuminates. If the initial energy is set too low, the check light will not illuminate. The check light is not designed for the use with inductive applicators.

For therapeutic procedures, various capacitive and inductive applicators are available. Applicators of various size are available to accommodate different size treatment areas. Applicators are connected to the rear of the main unit using the connector cable and are affixed to the adjustable arm.

With the capacitive field method, the treated body part is located in the high-frequency electric field between two insulated electrodes. The body and the applicators together form a capacitor. The transformation of electromagnetic energy into heat occurs in tissues of low blood circulation. Thus, the major amount of heat is generated in areas near the surface. While contact application causes intensive warming of superficial tissues, contactless application causes deeper warming. The inductive field method produces high-frequency electric currents within the body tissue by means of induction. These currents increase with increasing electric conductivity of the corresponding tissue region. The danger of excessive heating of the outer layers of tissue is therefore significantly reduced.

Individual treatment parameters can be manually set and adjusted by the operator. All treatment parameters can be set and saved as protocols as a reference for future therapy sessions.

The BTL Elite control unit continuously monitors the output of the system for safe operation. In addition, output can be terminated at any time during a treatment session by the patient pulling the safety switch. If the therapy is stopped by pulling the safety switch, the applicator immediately stops emitting electromagnetic energy and the unit switches to a pause mode. Patient safety is assured through a number of ways including proper maintenance of the system, operator training, and adherence to the general safety precautions and instructions provided in the user manual.

VI. Performance Data

The review of the technical characteristics, indications for use, and verification and validation information provided in the **510(k)** Premarket Notification demonstrates that the BTL Elite system is substantially equivalent to its predicate devices.

VII. Substantial Equivalence

The BTL Elite System is substantially equivalent to its predicate devices when used according to its intended use. This is based on the information provided in this **510(k)** Premarket Notification which demonstrates that the BTL Elite System shares the same technological characteristics, mechanism of action, intended use and physical properties when compared to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BTL Industries, Incorporated
% MMP Medical Associates, LLC
Ms. Marcy Moore
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OCT - 5 2012

Re: K120093
Trade/Device Name: BTL Elite
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: October 1, 2012
Received: October 5, 2012

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

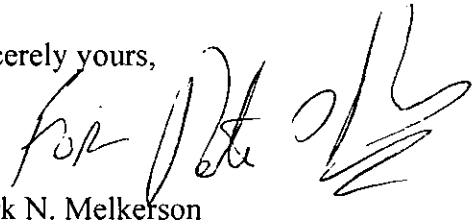
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: **BTL Elite**

Indications for Use: Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120093